09-22-06

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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pplicant:

FRIESEN et al.

Examiner:

Unknown

Serial No.:

o.: 10/584332

Group Art Unit:

Unknown

Filed:

June 23, 2006

Docket:

Date:

12695.0037USWO

Confirmation

2032

Notice of Allow.

N/A

No.:

Due Date:

September 23, 2006

Title:

COMBINATION THERAPIES EMPLOYING A COMPOSITION COMPRISING A HMG COA

REDUCTASE INHIBITOR AND A VITAMIN B6 RELATED COMPOUND

**CERTIFICATE UNDER 37 CFR 1.10:** 

"Express Mail" mailing label number: EV 841294748 US

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By: // Junker

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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PATENT TRADEMARK OFFICE

Sir:

We are transmitting herewith the attached:

Transmittal Sheet in duplicate containing Certificate of Mailing

☐ Information Disclosure Statement, Form 1449, 17 Reference(s)

Other: International Search Report, Form PCT/IB/326, Form PCT/IB/373, Form PCT/IB/237

Return postcard

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees a credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

Merchant & Gould P.C. P.O. Box 2903 Minneapolis, MN 55402-0903 612.332.5300

By: Name: Brian R. Dorn Reg. No.: 57,395

**BRD** 



10/584322

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I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450

## INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b))

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

## Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. Enclosed for the Examiner's information is a copy of the International Search Report. At least some of the references were recently cited in an International Search Report mailed May 10, 2005.

This statement should be considered because it is submitted within three months of the filing date of the above-identified application, which is not an application under 37 C.F.R. § 1.53(d). Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

A copy of any foreign patent document or "Other Document" listed on the Form 1449 is enclosed, in accordance with 37 C.F.R. §1.98(a)(2). Because this application was filed after June 30, 2003, copies of the U.S. Patents and U.S. patent publications listed on the enclosed Form 1449 are not provided.

A concise explanation of the relevance of each non-English language document or other information is as follows (37 C.F.R. §1.98(a)(3)):

An English translation has been provided for German reference 24 61 742

An English abstract has been provided for WIPO reference 2004/006919 A1 which was published in Japanese.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

23552

Respectfully submitted,

MERCHANT & GOULD P.C.

P.O. Box 2903

(612) **282-5300** 

Minneapolis, Minnesota 55402-0903

Dated: September 2,306

Brian R. Dorn

Reg. No. 57,395

BRD/ncb

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## FORMATION DISCLOSURE STATEMENT

IN AN APPLICATION (Use several sheets if necessary) Docket Number: 12695.0037USWO Application Number: 10/584,332

Applicant: FRIESEN et al.

Filing Date: June 23, 2006

Group Art Unit: Unknown

				U.S. PATENT DOCUMEN	VTS			
EXAMINER INITIAL	DOCUM	ENT NO.	DATE	NAME	CLASS	SUBCLASS		OPRIATE
	5,288,716		02-1994	Speck				,
	6,066,659		05-2000	Speck				
	2003/00493	14 A1	03-2003	Liang et al.				
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	2003/01144	24 A1	06-2003	Haque et al.			7	
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	<u> </u>		FOI	REIGN PATENT DOCUM	IENTS		<u> </u>	
	DOCUM	ENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANS	LATION
							YES	NO
	24 61 742		07-1976	Germany			Yes	
	97/38694		10-1997	WIPO				
	00/53606		09-2000	WIPO				
	00/57863		10-2000	WIPO				
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	2004/00691	9 A1	01-2004	WIPO			Abstract	
			<u> </u>					
	T			S (Including Author, Title,			· <del>-</del>	
		Brattstron et al. "Pyridoxine reduces cholesterol and low-density lipoprotein and increases antithrombin III activity in 80-year-old men with low plasma pyridoxal 5-phosphate" Scandanavian Journal of Clinical Laboratory Investigation 50 (1990) p. 873-876						
		Califf MD et al. "Myonecrosis After Revascularization Procedures" JACC Vol. 31 No. 2, (February 1998) p. 241-251  Chauhan, "Membrane dynamics, cholesterol homeostasis, and Alzheimer's disease" Journal of Lipid Research Volume 44, (2003) p. 2019-2029						
	Dumm et al. "Variations in the lipid profile of patients with chronic renal failure treated with pyridoxine" Lipids in Health and Disease (2003) 2(7) p. 1-6							

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

FORM 1449* INFORMATION DISCLOSURE ST	INFORMATION DISCLOSURE STATEMENT		Application Number: 10/584,332	
IN AN APPLICATION		Applicant: FRIESEN et al.		
(Use several sheets if necessa	ary)	Filing Date: June 23, 2006	Group Art Unit: Unknown	

The ESPRIT Investigators, "Novel dosing regimen of eptifibatide in planned coronary stent implantation (ESPRIT): a randomised, placebo-controlled trial" The Lancet Vol 356, (December 16, 2000) p. 2037-2044
Frohlich M.D., "Lipoproteins and homocyst(e)ine as risk factors for atherosclerosis: Assessment and treatment" Canadian Journal of Cardiology vol 11, Supplement C (May 1995) p. 18C - 23C
Hurt-Camejo et al. "Phospholipase A2 in Vascular Disease" Circulation Research 89 (2001) p. 298-304
Khayyal et al. "Effect of Magnesium Pyridoxal 5-Phosphate Glutamate on Vascular Reactivity in Experimental Hypercholesterolemia" Drugs Explt. Clin. Res XXIV(1) (1998) p. 29-40
Krishnamurthi et al. "Effect of Pyridoxal 5'-Phosphate (PALP) on Human Platelet Aggregation, Dense Granule Release and Thromboxane B <sub>2</sub> Generation - Role of Schiff Base Formation" Thromb Haemostas (Stuttgart) 48 (2) (1982) p. 136-141
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Wiklund et al. "Effects of simvastatin and atorvastatin on inflammation markers in plasma" Journal of Internal Medicine 251, (2002) p. 338-347

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EXAMINER DATE CONSIDERED

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